

QUESTIONS AND ANSWERS

For FSIS FORM 10,240-1 Production Information on Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products

Note: Questions # 13 f, 13g, 28 and 29 were added on 10/15/04

Questions # 30, 31, 32 and modification for #12 (in italics) were added on 10/22/04

1. QUESTION: Where can the form 10,240-1 be obtained?

ANSWER: The form can be downloaded from the FSIS website
http://www.fsis.usda.gov/forms/PDF/Form_10240-1.pdf
or can be requested from FSIS by calling 202-720-3219.

2. QUESTION: If an establishment produces only Alternative 2 products, should it return only page number 2 of the form or should it return all three pages with notation on pages 1 and 3 that no Alternative 1 or 3 products are produced?

ANSWER: The establishment can either submit all three pages with a note on pages 1 and 3 saying “no post-lethality exposed RTE products are produced with this Alternative”, or can submit only page 2 with a similar notation that it does not produce products under Alternatives 1 and 3.

3. QUESTION: Page 3 of the form (Alternative 3, Part 3C) asks what category (size) the plant is. How is that determined?

ANSWER: The category of a plant according to size (Large, Small and Very Small) is determined on the basis of the Small Business Administration’s definitions of a business and referenced in the Pathogen Reduction/HACCP final rule (61) FR 38806, as follows:

1. Large establishments are defined as all establishments with 500 or more employees
2. Small establishments are defined as all establishments with 10 or more employees but fewer than 500 employees.
3. Very small establishments are defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

4. QUESTION: Why is the plant category question asked only on Page 3 of the form?

ANSWER: The question on the size of the establishment was placed on the page for Alternative 3 questions because FSIS guidance on testing food contact surfaces varies according to the size category of the establishment. Since FSIS guidance for testing food contact surfaces for post-lethality exposed products under Alternatives 1 and 2 does not vary according to the size category of the establishment, this question was not necessary for RTE product produced under Alternative 1 or Alternative 2.

5. QUESTION: How is the establishment supposed to estimate their production volume? One year it may be 60,000 pounds but the establishment could get an order from one customer and increase production for that item for additional 100,000 pounds. Are previous year's records acceptable?

ANSWER: The establishment can utilize the previous year's production amounts or estimate the current year's production volume. Please note that on the bottom right of Page 4 of FSIS Form 10, 240-1, it states that producers should submit a revised form any time there is a significant change in volume of production.

6. QUESTION: On the form where it asks about "Annual Production" does FSIS want the total amount of finished product or the amount of Meat/Poultry used to manufacture the finished product?

ANSWER: The total amount of finished product produced in accordance with 9 CFR430 and without regard to the intended use of the product (e.g., for institutional purposes or retail sale).

7. QUESTION: When recording the annual volume, what basis should be used: previous actual annual production, or a projected total for the current year?

ANSWER: Either total will be sufficient. If the current year will differ significantly from the previous actual annual production, projected total for the current year is preferred.

8. QUESTION: Is the information provided by the plant available through the Freedom of Information Act?

ANSWER: No, this is proprietary information, and therefore exempt from disclosure.

9. QUESTION: The official establishment produces products under both FSIS and FDA jurisdiction. Should they report all products regulated by FDA and FSIS regulated?

ANSWER: No, report **only** the products subject to 9 CFR 430 Form 10,240-1.

10. QUESTION: Does the "Fully Cooked" category include the total of deli meats, hot dog products and other products?

ANSWER: No, the "Fully cooked" category refers to all other fully cooked products that are not included in the deli meats and hot dog categories.

11. QUESTION: The establishment produces 3 different products covered by Alternative 2. Should they all be totaled together on the same form?

ANSWER: Yes, all products under Alternative 2 should be entered on the same form.

12. QUESTION: If an establishment produces products that are not subject to the requirements of 9 CFR 430, does it need to complete and submit FSIS Form 10,240-1?

ANSWER: No, if an establishment's product is not subject to the regulatory requirements of 9 CFR 430, there would be no need for the establishment to complete any portion of the form or to send in a form.

RTE products that are not post-lethality exposed are not required to comply with 9 CFR 430.

Establishments are not *expected* to submit the survey form for the following types of RTE products *because they are not post-lethality exposed*:

- 1) fully cooked product in cook-in-bag that is shipped from the establishment in the intact cooking bag;
- 2) products receiving lethality treatment and hot-filled, provided the lethality temperature *and sanitary handling* are maintained *during the period of time in which the product moves from the point of lethality to the point of packaging. Establishments would need documentation on file which supports that the lethality temperature and sanitary handling are maintained continuously from the point of lethality to the point of packaging*; and
- 3) thermally processed commercially sterile products (canned products)

Non-RTE products are not covered by 9 CFR 430, e.g. partially cooked products; products intended for further processing and labeled for further processing. For these products, the establishment does not need to complete and submit the survey form.

13. QUESTION: Under which box would the following products listed below fit, since they are not listed on FSIS Form 10,240-1.

ANSWER: The items listed on each page of the form are examples only and are not all inclusive. Some examples of products not listed on the form:

a) Polish sausage (Would it be “fully cooked” or “hot dog”?)

If it has received a lethality which is sufficient to render it RTE, then it would be “Fully Cooked”. It would not be a “Hot Dog” product because polish sausage does not meet the food standard of identity of a Hot Dog as defined by 9 CFR 319.180

b) Fully cooked bone-in picnic shoulders and fully cooked bone-in hams that are not typically sliced and assembled into a sandwich

If these products have received lethality sufficient to render them RTE, these products would all be considered “Fully Cooked”.

c) Pork rinds, Chitterlings, Menudo

If these have received a lethality which is sufficient to render them RTE, then they would be “Fully Cooked”.

d) Beef sticks and summer sausage that are not fermented

If these unfermented products have been exposed to a lethality that is sufficient to result in a fully cooked ready to eat product, then they would be documented under “Fully Cooked Products”.

e) Does edible tallow, some of which bears the mark of inspection and goes for further processing for use in edible products and some does not, and is for further processing into cosmetics, soaps, etc., need to be identified on FSIS form 10, 240-1?

Those that are marked “for further processing” are not subject to the requirements of 9 CFR 430. Those that are not intended for further processing, bear no label “for further processing” and are considered post-lethality exposed RTE are subject to the requirements of 9 CFR 430.

f) Fully cooked hamburger and cheeseburger sandwiches (under voluntary inspection) which are kept frozen until the consumer microwaves them

Fully cooked hamburger and cheeseburger sandwiches are traditional, closed face sandwiches which include fully cooked hamburgers between two biscuits, bun, or bread, fall under the fully cooked category. These products are covered by the *Listeria* rule because in the preparation of the sandwiches, these fully cooked hamburgers are exposed to the post-cook or post-lethality environment.

g) Fully cooked chicken wings which are kept frozen until the consumer microwaves them

Fully cooked chicken wings fall under the fully cooked category and are also covered by the rule because these are post-lethality exposed during packaging.

14. QUESTION: How does an establishment determine the classification of its product?

ANSWER: In determining the classification of a product, the establishment has to determine the principal lethality treatment that the product receives or the lethality treatment that is sufficient to render the product RTE.

15. QUESTION: If an establishment indicated that it does not conduct any *Listeria* testing, should the plant be doing the testing?

ANSWER: The establishment should determine to what Alternative its product falls under and make its decision as to whether it needs to do testing based on the requirement of 9 CFR 430.

16. QUESTION: What method should be used to determine the proper category in Boxes 2 and 3 of any/each of the Alternatives when the product fits two or more categories (i.e. An “Other than Deli Product” such as fermented products that are sliced at the establishment but also sliced after distribution from establishment. An example would be hard salami or pepperoni that is sliced at the plant for distribution or at a deli for incorporation into a sandwich). Would the product be classified as Other than Deli/Fermented or as Deli/Sliced at Official Establishment and/or Deli/To be sliced after Distribution?

ANSWER: For these types of products, the establishment should place the product in the category where it poses the highest risk. For this product, an establishment can place it under Fermented Products or under Deli Products. However, since it is sliced at the establishment or sliced at the deli, it

should be placed under Deli Products since this is the higher risk category. Also, if the establishment slices and packages the product, the deli is not expected to slice it again. So for this product, placing it under Deli Products/Sliced and Packaged at the establishment would be a logical placement.

17. QUESTION: If sodium lactate is added to a product as an antimicrobial inhibitor. Where can an establishment get information on validation of Sodium Lactate?

ANSWER: When sodium lactate was used as an antimicrobial inhibitor in the product, there should be some documentation from the manufacturer. That documentation may have provided scientific studies as to how much lactate to add to the specific product and the effectiveness of the amount added in inhibiting the growth of *Listeria* through the shelf life of your product. The manufacturer of the lactate should be able to provide guidance on how to obtain the validation information. The compliance guidelines for control of *Listeria monocytogenes* in post lethality exposed product (on FSIS web site http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_97-013F.htm) have references to some scientific documentation that is available.

18. QUESTION: Pages 1 and 2 (Block 3) want to know about validated log reductions. What is meant by “validation”?

ANSWER: Validation is defined as the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard in a specific food. For example, an establishment that subjects its fully cooked, sliced, and repackaged product to steam pasteurization would consider its product to be under Alternative 1 or 2. To be able to consider the product in Alternative 1 or 2, the establishment must have supporting documentation that the treatment (steam pasteurization) will reduce the number of *L. monocytogenes* in the product by a certain number. This supporting documentation must come from a validation of the treatment. The validation of the treatment can be achieved by a challenge study or by using a published study applying the same time/temperature of treatment on the product and other factors in the study.

19. QUESTION: FSIS Notice 49-02 says that a company that “produces post lethality exposed RTE products...” must provide production information to FSIS. What is meant by “post-lethality exposed”?

ANSWER: Per 9 CFR 430.1, a ready to eat post-lethality exposed product is a product that comes into direct contact with a food contact surface after the lethality treatment in a post lethality processing environment. An example of post-lethality exposed product is sliced and packaged luncheon meat. The luncheon meat is first fully cooked in a bag, then taken out of the bag, sliced and repackaged. Fully cooking the product is the lethality treatment. After cooking (post-lethality) when the product is removed from its cooking bag and sliced, it is exposed to the post-lethality processing environment and can get contaminated with *L. monocytogenes*.

20. QUESTION: For an Alternative 2 product that is frozen, is the appropriate response to the "validated or highest increase in *L. monocytogenes* allowed" - "not applicable" or "less than 1 log?"

ANSWER: The appropriate response would be "less than 1 log" because there is no growth or outgrowth potential when products are frozen.

21. QUESTION: If a plant produces a barbeque product, (either beef or pork) is the tomato ketchup considered to be a secondary inhibitor if it has a pH of 4.7?

ANSWER: Generally, topical application of tomato ketchup with pH of 4.7 would not be considered an effective secondary inhibitor. However, to be able to qualify as an inhibitor or antimicrobial agent, both the exposed surface of the product in which *L. monocytogenes* can contaminate the product and the sauce should have a pH of less than 4.39 for an appropriate time (see Compliance Guidelines at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_97-013F.htm.) The establishment would need documentation to validate or support the antimicrobial activity of the antimicrobial agent.

22. QUESTION: Block B for Alternative 3 asks for the total percent of food contact surface (FCS) and environmental samples positive for *Listeria* spp. or *Listeria*-like organisms. The question does not differentiate between environmental and FCS test results. How will FSIS incorporate the differences in data from each type of sampling?

ANSWER: The objective of the question is to determine the effectiveness of sanitation since that is the control for *L. monocytogenes* in Alternative 3. Sanitation involves cleaning FCS and non-FCS in order to eliminate *L. monocytogenes* from the processing operation. In addition, since the frequency of FCS testing relative to environmental sampling is very low and the available data is small, both types of samples must be considered together for the data to be meaningful.

23. QUESTION: What if an establishment does not test food contact surfaces because the regulation does not require this in Alternative 1 or with a post-lethality treatment in Alternative 2? Should it put not applicable “NA” or does less than 2 times a year also include not testing?

ANSWER: A response of "less than 2 times" is not appropriate because it implies that some level of testing occurs. If no testing is conducted for Alternative 1 or Alternative 2 using a post-lethality treatment, please write "No testing done".

24. QUESTION: If a very small facility does not have lines, how is the question about “each line” to be answered?

ANSWER: A line is defined as the start of the process to the finished product. A line does not refer to a sequence of equipment. An establishment producing only 1 product would have at least one line.

25. QUESTION: How is “authorized official” defined? Is this the person named on the grant of inspection or can any designated person at my establishment complete and sign the form?

ANSWER: Each establishment should decide who within the organization is responsible for providing the information and signing the form.

26. QUESTION: Why does the form switch from year to month when asking about testing of food contact surfaces in Alternative 3 Block 3 A which asks about per month compared to Alternative 1 and 2 Block 3 C which is per year?

ANSWER: Because Alternative 3 product would present greater risk for becoming contaminated, if the food contact surface contains *Listeria monocytogenes*, and the product and process would not impede the growth of the pathogen throughout the expected shelf-life. Thus, verification of good sanitation is one way to demonstrate effectiveness of sanitation on a more frequent basis. The other alternative control measures have one or more steps to either reduce or eliminate the pathogen should it be present. Thus, sanitation is not the primary means of demonstrating effectiveness of the control measures.

27. QUESTION: If an establishment produces beef flavoring (paste) under USDA inspection, is it required to complete the form?

ANSWER: If the product is post-lethality exposed and is considered by your establishment to be used as a ready-to-eat product (i.e., will not undergo further lethality treatment by the consumer), then 9 CFR 430 is likely applicable and a form must be completed. If the product is labeled “for further processing” then 9 CFR 430 is not likely applicable and a form is not required.

28. QUESTION: For multi-component products like “lunchables” (contains meat, cheese, crackers, juice, etc.) or chicken Caesar salad (chicken, salad greens, dressing), for the “Annual production volume”, which one should be entered: a) the annual production volume of the entire product; or b) the annual production volume of the meat or poultry component?

ANSWER: For multi-component products where the meat or poultry component is separated from the other components in the package, such as in “lunchables”, only the annual production volume estimate for the meat or poultry component should be reported. For multi-component products where the meat or poultry component is mixed and in contact with all the other ingredients, such as in chicken Caesar salad, the production volume estimate for the entire product should be reported.

29. QUESTION: If an establishment tests food contact surfaces one time per week, taking 6 different samples each time, with a total of 24 samples each month, which answer should the establishment check: a) 4 times a month; or b) more than 4 times a month?

ANSWER: The establishment can check “4 times” per month in the block for testing food contact surfaces. The frequency of testing is one time a week regardless of the number of samples.

30. QUESTION: An establishment produces a number of different products under the same product category (e.g., deli products sliced and packaged at the official establishment) but each product either has a different validated log reduction or number of times the food contact surface (FCS) is tested per month. Should the establishment check each appropriate box for the same block (e.g., 3 checks for Block 3.A.) or complete a separate form for each product in the Alternative?

ANSWER: If the establishment has more than one product under a product category, it should use a separate form for each product because each product may differ in production volume, log reduction achieved, the amount of growth of *L. monocytogenes* allowed by the antimicrobial agent or process, or the number of times a FCS is tested. For example, for the product category “Deli products sliced and packaged at the official establishment”, if the establishment has two or more different products, it should complete one form for each product, particularly addressing both Block 2 and Block 3. If, for example, the products are different within the category (e.g., sliced roast beef versus sliced roast pork)

but the lethality reduction, amount of growth of *L. monocytogenes*, and FCS testing are the basically the same, then only one form should be completed but the volume of production should reflect the total volume for the product category.

31. QUESTION: Is a spray-dried meat or poultry fat product considered to be RTE as per 9 CFR 430.4 (d)?

ANSWER: Since the spray-dried meat or poultry product receives a full cook and is shelf stable, FSIS considers it to be RTE (refer to the definition of RTE contained in Attachment 2 of the Compliance Guidelines). If it is a post-lethality exposed product, it is covered by the rule. However, if the product is packaged immediately after the lethality treatment such that there is no exposure to the post-lethality environment during packaging (or the exposure is addressed through special sanitary handling), and the establishment has documentation to support this, the product can be considered by the establishment to not be post-lethality exposed and therefore not covered by the rule.

32. QUESTION: Should the Form 10,240-1 be completed for fully cooked pickled pig's feet and pickled cooked sausage?

ANSWER: Fully cooked pickled pig's feet and pickled cooked sausage are both considered by FSIS to be RTE products that are exposed to the environment prior to packaging and are covered by 9 CFR 430. Therefore, Form 10,240-1 should be completed for these products.